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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,868	12/11/2003	Randy Westlund	GUID.076PA (02-046)	8097
51294	7590	05/22/2006	EXAMINER	
HOLLINGSWORTH & FUNK, LLC 8009 34TH AVE S. SUITE 125 MINNEAPOLIS, MN 55425			JASTRZAB, JEFFREY R	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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# Office Action Summary

Application No.

10/733,868

Applicant(s)

WESTLUND

Examiner

Jeffrey R. Jastrzab

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed 5/2/06 have been fully considered but they are not persuasive. Applicants have added the language "yet facilitate electrical stimulation of cardiac tissue" to the claims in an attempt to clarify the function of the fluoropolymer coating. Applicants argue that the tissue stimulating surface in the Salo reference is free of insulation and does not have a coating or sleeve as claimed, and that the claimed coating or sleeve, which is provided on a majority of that exposed surface, is sufficient in coverage to inhibit exit block yet facilitate stimulation of cardiac tissue. Applicants further state that the exposed surface of the fixation arrangement, when read in light of the specification, refers to the tissue stimulating surface of the electrode.

What is in question is the breadth of the function associated with the coating or sleeve as well as the meaning of "on a majority of the active fixation arrangement".

These issues will be addressed separately as follows:

First, the claim currently calls for "sufficient coverage (of the active fixation arrangement) to inhibit exit block yet facilitate stimulation of cardiac tissue". This issue is a matter of degree. The simple fact that the helix in Salo is partially insulated creates a situation of inhibiting exit block to some degree dependent upon the extent of the insulation. Since the entire helix is not insulated, clearly electrical stimulation is facilitated.

Second, the claim language encompasses a vast range of possibilities including, *inter alia*, full coverage of the electrode surface with a coating that has discontinuities or

voids, partial coating on, for example 75%, of the active fixation device, or the like. In fact, Applicants' specification explicitly calls for the exposed surface to be one of several options as follows:

*"layer 425 thereby typically covers most or all of the exposed helical electrode 420, but may **alternately include voids, apertures, or other discontinuities.** (emphasis added) The polymer layer 425 solicits less tissue inflammation and reduces the amount of fibrotic tissue around the implant site, reducing exit block development"*

It is precisely the "voids, apertures, or other discontinuities" embodiment described by Applicants that allows the Salo et al. structure to continue to read on the claims as written. The Examiner agrees that the Salo insulation covers a portion of the stimulation electrode or active surface. Applicants seem to be arguing that since insulation exists in Salo, that the surface can no longer be considered active. In response, the absence of electrical insulation on a part of the Salo electrode is the same as a void or discontinuity or aperture as described in applicants' specification, i.e. the insulation is discontinuous to the end of the helix, or rather, the electrode is devoid of insulation at its tip. The mere fact that insulation exists on the Salo helix does not render the entire active fixation element inactive, but instead provides for only a portion of the surface to be covered and inactive. This is structurally equivalent to the disclosed voids and functionally equivalent insofar as polymer with voids or apertures would provide a degree of exit block commensurate in scope with the exposed surface area of the electrode. Since Salo includes an insulated portion, it inherently exhibits a degree

of exit block and since Salo also does not completely insulate the helix, it is inherently capable of facilitating electrical stimulation as now claimed. With Applicant's coating, the entire fixation arrangement is not active, but only those portions that are exposed. Both situations amount to exposing an electrode's active surface through an absence of insulation, void, aperture, or discontinuity. As such, the rejections of record stand.

In response to applicants arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As such, the Examiner's previous arguments on the combinability of the references as stated in the Final Rejection of 1/26/06 apply equally here.

### ***Claim Rejections - 35 USC § 103***

Claims 1, 3, 6, 8, 11-14, 16, 19, 21, 24, 25, 27, 30, 31 and 33 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Salo et al., US 5,728,140, in view of Helland et al, US-5,545,210 for the reasons of record.

Claims 2, 4, 7, 9, 15, 17, 20, 22, 26, 28, 32 and 34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Salo et al., US 5,728,140, in view of Helland et al, US-5,545,210 and further in view of Carson, US 5,931,862 for the reasons of record.

Claims 5, 10, 18, 23, 29 and 35 are rejected as being unpatentable over Salo et al., US 5,728,140, in view of Helland et al, US-5,545,210 and further in view of Stokes et al. H356 for the reasons of record.

***Continued Examination Under 37 CFR 1.114***


All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Jastrzab whose telephone number is (571) 272-4947. The examiner can normally be reached on Monday - Thursday 5:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jeffrey R. Jastrzab  
Primary Examiner  
Art Unit 3762  
5/14/06